LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Cardovia
(bisoprolol fumarate)

SE/H/2519/01-06/DC

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Summary Public Assessment Report

Cardovia
bisoprolol fumarate

Film-coated tablet, 1,25 mg, 2,5 mg, 3,75 mg, 5 mg, 7,5 mg, 10 mg

This is a summary of the public assessment report (PAR) for Cardovia. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cardovia and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Emconcor CHF.

- Cardovia is used to treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides). Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs.

- Cardovia 5 mg and 10 mg are also used to treat high blood pressure (hypertension) and chest pain caused by blockages in the arteries that supply the heart muscle (angina pectoris).

How does Cardovia work?

The active substance in Cardovia is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body`s response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

How is Cardovia used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Cardovia have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Emconcor CHF. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Cardovia?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Cardovia?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Emconcor CHF, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Cardovia?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Cardovia

The full PAR for Cardovia can be found on the following website: MRI - Home. For more information about treatment with Cardovia, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-04.